REMARKS/ARGUMENTS

Claims 1, 3-7, 9-21 and 24-25 were pending at the time of the mailing of the outstanding Office Action. By this amendment, all pending claims have been amended to recite an implant comprising a coating system, rather than the coating system itself. No claims have been added or cancelled.

In the Office Action of 3 April 2009, claims 1, 3-7, 9-21 and 24-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot (U.S. Pat. Pub. No. 2003/0236567, hereinafter "Elliot") in view of Collombel et al. (U.S. Pat. No. 5,166,187, hereinafter "Collombel") and Pastorello et al. (U.S. Pat. No. 6,642,213, hereinafter "Pastorello"). Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot/Collombel in view of Pastorello and Swan (U.S. Pat. No. 5,563,056, hereinafter "Swan"). Claims 1, 3-7, and 9-20 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen (U.S. Pat. No. 6,685,626, hereinafter "Wironen") and Collombel in view of Pastorello. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen/Collombel in view of Pastorello and Swan.

In the Office Action, it was maintained that Elliot teaches an implantable prosthesis which can be composed of hyaluronic acid and chitosan but does not teach the rate of degradation of the polysaccharide layer. It was additionally maintained that Collombel provides the usage of chitosan as a prosthesis coating and that the rate of degradation can be adjusted according to the molecular weight and degree of acetylation of the chitosan. It was further maintained that Pastorello teaches that the degradation time of an implant containing a hyaluronic acid derivative can be adjusted by amount of esterification of the hyaluronic acid.

Claims 1 and 13 have been amended to recite an implant having a metallic main body and a coating, and that the degradation rate of the polysaccharide layer is adjusted by the crosslinking of the hyaluronic acid and/or hyaluronic acid derivatives with a variety of specified agents. Support for this amendment may be found in the specification at paragraphs 0025 and 0026. However, polyanhydrides are specifically excluded from the recited agents. As a result, esterification is excluded as a source of crosslinking in the polysaccharide layer as recited in the claims as amended. Esterification is disfavored as a crosslinking method because hydrolyzation of the ester bond can result in the production of carboxylic acid, which may

lower the pH, which may not be well tolerated by the tissues in the area of the implant. Therefore, Pastorello, which teaches crosslinking of hyaluronic acid by esterification, can not be relied upon for establishing a *prima facie* case of obviousness of the claims.

Furthermore, one of ordinary skill in the art would not have been motivated to look to Elliot for a teaching regarding a degradable implant. Elliot does not teach the desirability of any degradation by any part of an implant. In fact, Elliot provides a prosthesis which is intended "to replace a portion of a bodily passageway" (paragraph 0020) to treat conditions such as abdominal aortic aneurysm (Abstract). As such, degradation of the prosthesis could cause leaks or even failure of the prosthesis, which would be highly undesirable (see paragraph 0006).

Also, Collombel also does not teach or suggest a coating for an implant having a metallic main body. Collombel provides a chitosan-containing composition primarily as an artificial skin. The only teaching or suggestion of use of a chitosan compound as a coating on an implant is in connection with silicon or Dacron prostheses to prevent slipping of the prosthesis (Example 4). One of ordinary skill in the art would not look for guidance from Collombel regarding an implant having a metal main body.

However, even assuming, *arguendo,* that the teachings of Collombel would be recognized by one of ordinary skill in the art as being applicable to implants having a metallic main body as alleged, such a combination would change a principle of operation of both Elliot and Collombel. Such a modification is impermissible under MPEP 2143.01; VI. To combine Elliot and Collombel, the implant would necessarily change from an implant in which maintenance of structural integrity is paramount, as in Elliot, to one in which degradation is recognized, desired and manipulated. The combination would also necessarily change the coating from one for a polymeric implant, as in Collombel, to one for a metallic implant. Therefore, proposed combination of Elliot with Collombel and Pastorello would alter principles of operation of Elliot and Collombel, rendering such a combination non-obvious. One of ordinary skill in the art would not have had a reasonable expectation of success in combining the teachings of Collombel and/or Pastorello with those of Elliot.

For the reasons provided above, the Applicants maintain that independent claims 1 and 13 patentably distinguish over Elliot, Collombel and Pasterello, either individually or in combination. Likewise, claims 3-7, 9-12, 14-20 and 24-25, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Elliot, Collombel

and Pasterello. Withdrawal of the rejection of claims 1, 3-7, 9-21 and 24-25 under 35 U.S.C. § 103(a) as unpatentable over Elliot in view of Pasterello and Collombel is requested.

Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot/Collombel in view of Pastorello and Swan. The comments provided above regarding Elliot, Collombel and Pastorello are repeated herein with respect to this rejection of claim 21. Therefore, the Applicants maintain that claim 21 also patentably distinguishes over Elliot, Collombel, Pasterello and Swan. Withdrawal of this rejection of claim 21 under 35 U.S.C. § 103(a) is also requested.

Similarly, claims 1, 3-7, and 9-20 were rejected as being obvious over Wironen and Collombel in view of Pastorello. Distinctions between Pastorello and the present invention and between Collombel and the present invention are provided above and are repeated with regard to this rejection. As stated previously, Wironen provides a coating for a metallic implant that includes hyaluronic acid and chitosan only for a limited purpose – the creation of adhesions between implants and anatomical structures to stabilize implants. One of ordinary skill in the art would not have found any suggestion or motivation to combine the adjustable biodegradation properties of a compound containing either hyaluronic acid or chitosan (neither of which is disclosed as suitable for use as a coating) with an adhesion-promoting composition of Wironen to arrive at the present invention as recited in amended claims 1 or 13.

Therefore, the Applicants also maintain that independent claims 1 and 13 patentably distinguish over Wironen, Pasterello and Collombel, either individually or in combination. Likewise, claims 3-7, 9-12, and 14-19, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Wironen, Pasterello and/or Collombel. Withdrawal of the rejection of claims 1, 3-7, and 9-20 under 35 U.S.C. § 103(a) as unpatentable over Wironen in view of Pasterello and Collombel is requested.

Finally, claims 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen/Collombel in view of Pastorello and Swan. In light of the Applicants' comments above regarding each of these references, which are repeated with regard to the present rejection, the Applicants maintain that claim 21 also patentably distinguishes over Wironen, Collombel , Pastorello, and Swan, either individually or in combination. Withdrawal of this rejection of claim 21 under 35 U.S.C. § 103(a) is respectfully requested.

The outstanding Office action was mailed on 3 April 2009. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for a three month extension of time for response is hereby made. The Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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